

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
)	MDL NO. 1203
)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8907

Bartle, J.

July 11, 2012

Carol M. Rounds ("Ms. Rounds" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Rob D. Rounds, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In September, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert E. Fowles, M.D., F.A.C.C. Dr. Fowles is no stranger to this litigation. According to the Trust, he has signed at least 109 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated March 26, 2002, Dr. Fowles

3. (...continued)

for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

attested in Part II of claimant's Green Form that Ms. Rounds suffered from severe mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$462,103.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Alan A. Gabster, M.D., stated that Ms. Rounds had left atrial enlargement with a left atrial dimension of 44 mm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b)ii). Dr. Gabster also measured claimant's ejection fraction to be 72%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is

4. Dr. Fowles also attested that claimant suffered from moderate aortic regurgitation and New York Heart Association Functional Class I symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant has an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim.

measured as less than or equal to 60%. See id.

§ IV.B.2.c.(2)(b)iv).

In November, 2005, the Trust forwarded the claim for review by Vincent L. Sorrell, M.D., F.A.C.P., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Sorrell determined that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension or a reduced ejection fraction in the range of 50% to 60%. Specifically, Dr. Sorrell measured claimant's left atrial antero-posterior dimension to be 37 mm and her left atrial supero-inferior dimension to be 50 mm. In addition, he explained that "[t]he [left atrial antero-posterior dimension] shown on the video was off-axis." With respect to claimant's ejection fraction, Dr. Sorrell noted that "[t]he [left ventricular ejection fraction] was entirely normal at >60%."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the claim of Ms. Rounds.

In contest, claimant argued that there was a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension.⁷ In support, Ms. Rounds submitted a notarized letter from Richard L. Callihan, M.D.,⁸ who asserted that claimant had an abnormal left atrial dimension. Specifically, Dr. Callihan wrote, in pertinent part, that:

Mild [left atrial enlargement] is present based upon accurate m-mode measurement of the left atrial [antero-posterior] dimension (44 mm) in the parasternal long-axis view at the level of the aortic valve. The measurement is taken from the leading edge of the posterior aortic wall to the leading edge of the posterior wall of the left atrium (as recommended by the ASE).

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review.

Dr. Sorrell submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that claimant suffered from an abnormal left atrial dimension. Specifically, Dr. Sorrell stated:

I properly measured [c]laimant's left atrial dimension in the same frame in the

7. Ms. Rounds did not contest the Trust's determination that there was no reasonable medical basis for the attesting physician's representation that claimant had a reduced ejection fraction in the range of 50% to 60%. In fact, Dr. Callihan noted that claimant's "[l]eft ventricular function is qualitatively greater than 60% and measured at 72%."

8. Dr. Callihan also is no stranger to this litigation. According to the Trust, he has signed at least 1,089 Green Forms on behalf of claimants seeking Matrix Benefits.

parasternal long-axis view as [c]laimant's sonographer. I measured it at no more than 3.8 cm. Claimant's measurement was incorrectly performed on a diagonal, inflating the measurement of the dimension.

The Trust then issued a final post-audit determination again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On June 21, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6384 (June 21, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on September 27, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two
(continued...)

the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of

9. (...continued)
outstanding experts who take opposite positions" is proper. Id.

an abnormal left atrial dimension. Specifically, Dr. Abramson stated that:

The left atrium measurement on the tape was incorrectly obtained on an oblique angle; therefore the dimension obtained by the technologist (4.4 cm) on the tape is larger than the true dimension.

I measured the left atrium in both acceptable views (as per the Green Form). I measured the left atrial diameter in three different cardiac cycles in the parasternal long axis view at 3.7 cm, 3.7 cm, and 3.8 cm, all of which are within normal limits. The Green Form defines an abnormal left atrium in this view as >4.0 cm. I also measured the left atrial dimension in the supero-inferior axis in the apical-4-chamber view at 4.7 cm, 4.8 cm and 4.9 cm. The Green Form defines an abnormal left atrial dimension in this view as >5.3 cm. These values are all within normal limits. This is a normal-sized left atrium.

In summary, I believe that this left atrium is normal-sized, even allowing for inter-reader variability. I believe there is no reasonable medical basis for the Attesting Physician to find this claimant's left atrium to be dilated.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As stated above, the Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b)ii). Here, both Dr. Sorrell and Dr. Abramson

found that claimant's left atrial antero-posterior systolic dimension measured no more than 3.8 cm in the parasternal long-axis view. In addition, Dr. Sorrell observed that "[t]he [left atrial antero-posterior dimension] shown on the video was off-axis," and Dr. Abramson concluded that "[t]he left atrium measurement on the tape was incorrectly obtained on an oblique angle; therefore the dimension obtained by the technologist (4.4 cm) on the tape is larger than the true dimension."¹⁰ While claimant's expert, Dr. Callihan, opines that "the measurement is taken from the leading edge of the posterior aortic wall to the leading edge of the posterior wall of the left atrium," he does not address whether the image is off-axis.¹¹ Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnoses and Green Form answer.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had an abnormal left atrial dimension. Therefore, we will affirm the Trust's denial of the claim of Ms. Rounds for Matrix Benefits and the related derivative claim submitted by her spouse.

10. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

11. None of claimant's physicians identified a supero-inferior dimension greater than 5.3 cm in the apical four chamber view.